

CHAPTER 19
NONRESIDENT PHARMACY LICENSES

657—19.1(155A) Definitions.

“Board” means the Iowa board of pharmacy examiners.

“Home state” means the state in which a pharmacy is located.

“Nonresident pharmacy” means a pharmacy located outside the state of Iowa which delivers, dispenses, or distributes, by any method, prescription drugs or devices to an ultimate user physically located in this state. “Nonresident pharmacy” shall include a pharmacy located outside the state of Iowa which provides routine pharmacy services to an ultimate user in this state.

“Nonresident pharmacy license” means a pharmacy license issued to a nonresident pharmacy.

“Pharmacy service” includes, but is not limited to, product and nonproduct services such as delivering, dispensing, or distributing prescription drugs or devices, providing patient counseling and drug information, assessing health risks, and participating in pharmaceutical care planning.

657—19.2(155A) Application and license requirements. A nonresident pharmacy shall apply for and obtain a nonresident pharmacy license from the board prior to providing pharmacy services to an ultimate user in this state. Change of pharmacy name, ownership, location, or pharmacist in charge shall require a new completed application and license fee pursuant to 657—subrules 3.4(3) to 3.4(6).

19.2(1) A nonresident pharmacy license shall expire on December 31 of each year. The fee for a new or renewal license shall be \$100. A nonresident pharmacy license form shall be issued upon receipt of the license application information required in subrule 19.2(2) and payment of the license fee.

Failure to renew the license before January 1 following expiration shall require a renewal fee of \$200. Failure to renew the license before February 1 following expiration shall require a renewal fee of \$300. Failure to renew the license before March 1 following expiration shall require a renewal fee of \$400. Failure to renew the license before April 1 following expiration shall require an appearance before the board and a renewal fee of \$500. In no event shall the fee for late renewal of the license exceed \$500.

19.2(2) A nonresident pharmacy shall submit all of the following in order to obtain or renew a nonresident pharmacy license:

a. A completed application form, available from the board, and an application fee as provided in subrule 19.2(1).

b. Evidence of possession of a valid license, permit, or registration as a pharmacy in compliance with the laws of the home state. Such evidence shall consist of one of the following:

(1) Copy of the current license, permit, or registration certificate issued by the regulatory or licensing agency of the home state; or

(2) Letter from the regulatory or licensing agency of the home state certifying the pharmacy’s compliance with the pharmacy laws of that state.

c. A copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the home state.

d. Evidence of correction of any noncompliance noted on inspection reports of the regulatory or licensing agency of the home state and all other regulatory agencies.

e. A list of the names, titles, and home addresses of all principal owners, partners, and officers of the nonresident pharmacy.

f. A list of the names and license numbers of all pharmacists and, if available, the names and license or registration numbers of all supportive personnel employed by the nonresident pharmacy who deliver, dispense, or distribute, by any method, prescription drugs to an ultimate user in this state, and the name, license number, and signature of the pharmacist in charge of the nonresident pharmacy.

g. A copy of the nonresident pharmacy's policies and procedures regarding the records of controlled substances delivered, dispensed, or distributed to ultimate users in this state to be maintained and detailing the format and location of those records. If policies and procedures are unchanged since previously submitted to the board, the applicant shall so indicate and need not include a copy with the application for license renewal or change.

h. A copy of the nonresident pharmacy's policies and procedures evidencing that the pharmacy provides, during its regular hours of operation for at least 6 days and for at least 40 hours per week, toll-free telephone service to facilitate communication between ultimate users in this state and a pharmacist who has access to the ultimate user's records in the nonresident pharmacy, and that the toll-free number is printed on the label affixed to each container of prescription drugs delivered, dispensed, or distributed in this state. A copy of a prescription label including the toll-free number shall be included. If policies and procedures are unchanged since previously submitted to the board, the applicant shall so indicate and need not include a copy with the application for license renewal or change.

19.2(3) A nonresident pharmacy shall update lists required by subrule 19.2(2), paragraphs "e" and "f," within 30 days of any addition, deletion, or other change to a list.

657—19.3(155A) Discipline. Pursuant to 657—Chapters 35 and 36, the board may deny, suspend, or revoke a nonresident pharmacy license for any violation of Iowa Code section 155A.13A; section 155A.15, subsection 2, paragraph "a," "b," "d," "e," "f," "g," "h," or "i"; Iowa Code chapter 124, 124A, 124B, 126, or 205; or a rule of the board promulgated thereunder unless the Iowa Code or Iowa Administrative Code conflicts with law, administrative rule, or regulation of the home state. The more stringent of the two shall apply when there is a conflict of law regarding services to Iowa residents.

657—19.4(155A) Training and utilization of pharmacy technicians. Nonresident pharmacies utilizing pharmacy technicians shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians. Pharmacy policies shall specify the frequency of review. Technician training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of technician training shall be available for inspection by the board or an agent of the board.

657—19.5(135C,155A) Personnel histories. Pursuant to the requirements of Iowa Code section 135C.33, the provisions of this rule shall apply to any pharmacy employing any person to provide patient care services in a patient's home within the state of Iowa. For the purposes of this rule, "employed by the pharmacy" shall include any individual who is paid, either by the pharmacy or by any other entity such as a corporate entity, a temporary agency, or an independent contractor, to provide treatment or services to any patient in the patient's home in Iowa. Specifically excluded from the requirements of this rule are individuals such as delivery persons or couriers who do not enter the patient's home for the purpose of instructing the patient or the patient's caregiver in the use or maintenance of the equipment, device, or medication being delivered, or who do not enter the patient's home for the purpose of setting up or servicing the equipment, device, or medication used to treat the patient in the patient's home.

19.5(1) Applicants questioned, informed. The pharmacy shall ask the following question of each person seeking employment in a position which will provide in-home services in Iowa: "Do you have a record of founded child or dependent adult abuse or have you ever been convicted of a crime, in this state or any other state?" The applicant shall also be informed that a criminal history and dependent adult abuse record check will be conducted. The applicant shall indicate, by signed acknowledgment, that the applicant has been informed that such record checks will be conducted.

19.5(2) Procedures and forms. Prior to the employment of any person to provide in-home services in Iowa, the pharmacy shall submit a form specified by the department of public safety to the department of public safety and receive the results of a criminal history check and dependent adult abuse record check. The pharmacy may submit a form specified by the department of human services to the department of human services to request a child abuse history check.

19.5(3) Employment prohibition—exception. A person who has a criminal record, founded dependent adult abuse report, or founded child abuse report shall not be employed by a pharmacy to provide in-home services in Iowa unless the department of human services has evaluated the crime or founded abuse report and concluded that the crime or founded abuse does not merit prohibition from such employment.

19.5(4) Records. The pharmacy shall keep copies of all record checks and evaluations.

657—19.6(155A) Reference library. References may be printed or computer-accessed. A reference library shall be maintained which includes, as a minimum, one reference from each of the following categories. A pharmacy may request waiver or variance from a provision of this rule pursuant to the procedures and requirements of 657—1.3(17A,124,126,147,155A,205,272C).

1. Current Iowa pharmacy laws, rules, and regulations.
2. A patient information reference, updated at least annually, such as:
 - United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient);
 - Facts and Comparisons Patient Drug Facts; or
 - Leaflets which provide patient information in compliance with rule 657—8.20(155A).
3. A current reference on drug interactions, such as:
 - Phillip D. Hansten's Drug Interactions; or
 - Facts and Comparisons Drug Interactions.
4. A general information reference, updated at least annually, such as:
 - Facts and Comparisons with current supplements;
 - United States Pharmacopeia Dispensing Information, Volume I (Drug Information for the Healthcare Provider); or
 - American Hospital Formulary Service with current supplements.
5. A current drug equivalency reference, including supplements, such as:
 - Approved Drug Products With Therapeutic Equivalence Evaluations (FDA Orange Book);
 - ABC - Approved Bioequivalency Codes; or
 - USP DI, Volume III.
6. Basic antidote information or the telephone number of a poison control center.
7. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served.

657—19.7(155A) Confidential and electronic data. The pharmacist in charge shall be responsible for developing, implementing, and enforcing policies and procedures to ensure patient confidentiality and to protect patient identity and patient-specific information from inappropriate or nonessential access, use, or distribution pursuant to the requirements of 657—Chapter 21.

657—19.8(124,155A) Storage and shipment of drugs and devices. The pharmacist in charge shall be responsible for developing, implementing, and enforcing policies and procedures to ensure compliance with 657—6.7(155A) and USP standards for the storage and shipment of medications and devices. Policies and procedures shall provide for the shipment of controlled substances via a secure and traceable method and all records of such shipment and delivery to Iowa patients shall be maintained for a minimum of two years from date of delivery.

657—19.9(155A) Patient records, prospective drug review, and patient counseling.

19.9(1) *Patient records.* A patient record system shall be maintained pursuant to 657—8.18(155A) for Iowa patients for whom prescription drug orders are dispensed.

19.9(2) *Prospective drug review.* A pharmacist shall, pursuant to the requirements of 657—8.19(155A), review the patient record and each prescription drug order presented for initial dispensing or refilling.

19.9(3) *Patient counseling.* The pharmacist in charge shall be responsible for developing, implementing, and enforcing policies and procedures to ensure that Iowa patients receive appropriate counseling pursuant to the requirements of 657—8.20(155A).

These rules are intended to implement Iowa Code sections 124.306, 155A.13, 155A.13A, 155A.31, and 155A.35.

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